## UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

SEAN HERRING, on his own	behalf )	
and on behalf of all others simi	ilarly situated, )	
	)	
I	Plaintiff, )	No. 14-cv-5076
v.	)	
	)	
HEALTH CARE SERVICE CORPORATION,		
	)	
I	Defendant. )	

#### **CLASS ACTION COMPLAINT**

Plaintiff Sean Herring ("Plaintiff"), complains as follows on his own behalf and on behalf of all others similarly situated, against Defendant Health Care Service Corporation ("Defendant" or "HCSC").

#### INTRODUCTION

- 1. Plaintiff is a participant in the Sandia National Labs PPO plan (the "BCBS Plan"), a group health benefit plan sponsored by Plaintiff's private-sector employer. The BCBS Plan is governed by the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §1001, *et seq.*, and is administered by HCSC through one of its health insurance divisions that operates under the name Blue Cross Blue Shield of New Mexico ("BCBSNM").
- 2. Plaintiff suffers from Major Depressive Disorder, which has not been alleviated by psychotherapy or administration of anti-depressant medication. In 2013, Plaintiff's treating psychiatrist, Reuben Sutter, M.D. ("Dr. Sutter"), recommended that Plaintiff undergo therapeutic repetitive transcranial magnetic stimulation ("TMS") therapy. BCBSNM, however, denied

Plaintiff's request for pre-authorization for TMS therapy on the ground that it fell under the BCBS Plan's "Experimental or Investigational Services" exclusion.

- 3. Following BCBSNM's denial of coverage, Plaintiff exhausted all appeals provided by the Plan. BCBSNM responded to each level of appeal by upholding the denial of coverage.
- 4. In so denying coverage, HCSC followed a uniform policy of denying coverage for TMS therapy for all participants in ERISA plans whose terms of coverage were governed by policies issued by HCSC.
- 5. As further described in this Complaint, TMS therapy is a proven, efficacious treatment for depression, has been approved for such use by the Food and Drug Administration (FDA), and is not experimental or investigational within the meaning of that term as defined in the Plan or in similar Plans whose terms are governed by policies issued by HCSC. Defendant's denial of coverage for Plaintiff and members of a class Plaintiff seeks to represent therefore violated the terms of the relevant Plans.
- 6. Under ERISA, Plaintiff and the members of the class he seeks to represent are entitled to equitable and declaratory relief reversing Defendant's benefits denials, enjoining application of its erroneous medical policy, and awarding monetary and other ancillary relief. As further described herein, Plaintiff and that class are likewise entitled to equitable and declaratory relief enjoining Defendant from its unlawful policy of requiring preauthorization of any mental health treatment, a policy which violates the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 29 U.S.C. §1185a ("Federal Parity Act" or "MHPAEA").

#### THE PARTIES

7. Plaintiff is insured under the BCBS Plan, pursuant to which he has sought coverage for TMS therapy. Plaintiff resides in Albuquerque, New Mexico.

8. Defendant HCSC, headquartered in Chicago, Illinois, issues and administers health care plans in five states through five divisions, operating, respectively, under the names of BCBSNM, Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas. HCSC authored and distributed the medical policy BCBSNM relied on to exclude coverage for the TMS therapy services requested by Plaintiff.

### JURISDICTION AND VENUE

- 9. Defendant's actions in administering employer-sponsored health care plans, including making coverage and benefit determinations under the terms and conditions of the health care plans, are governed by ERISA. This Court has jurisdiction of this case under 28 U.S.C. §1331 (federal question jurisdiction) and 29 U.S.C. §1132(e) (ERISA).
- 10. Venue is appropriate in this District because Defendant HCSC is headquartered here, and because the medical policy challenged herein was developed in, and distributed from this District.

#### FACTUAL ALLEGATIONS

- 11. The vast majority of the health plans underwritten and/or administered by Defendant are employee welfare benefit plans sponsored by private-sector employers ("ERISA Plan"). Such plans, including the BCBS Plan, are governed by ERISA.
- 12. During all relevant times, the Defendant acted as a fiduciary with respect to its administration of ERISA plans. In particular, the Defendant interpreted and applied ERISA plan terms, made coverage and benefit decisions, and provided payment to participants and their providers. Accordingly, under ERISA, the Defendant was required to, among other things, comply with the requirements imposed by ERISA for administering ERISA plans, make benefit determinations in accordance with ERISA plan terms and conditions (unless doing so would

otherwise violate ERISA), and afford participants and beneficiaries an opportunity to obtain "full and fair review" of any denied or reduced reimbursements.

### **HCSC's Denial of Coverage for Plaintiff's TMS Therapy**

- 13. Plaintiff has been in treatment for chronic depression for many years. While Plaintiff's doctors attempted to treat him with a variety of anti-depressant medications, such medications proved to be ineffective in alleviating Plaintiff's long-term symptoms. Plaintiff also periodically suffered severe adverse reactions to such medications.
- 14. Since 2004, Plaintiff has also undergone talk therapy with numerous psychotherapists, including Dr. Reuben Sutter.
- 15. In 2013, Dr. Sutter recommended that Plaintiff undergo TMS therapy using a device known as the NeuroStar TMS System. TMS is a treatment for major depressive disorder that involves the non-invasive delivery of repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the patient's cerebral cortex to treat depression symptoms without inducing seizure.
- 16. Plaintiff's BCBS Plan, which was issued by BCBSNM on behalf of Plaintiff's employer, includes the following provision in its Program Summary:

**Preauthorization for Behavioral Health**. Preauthorization for behavioral health (mental health or Chemical Dependency) is required before receiving inpatient and Outpatient services whether in-network...or out-of-network.

\* \* \*

If Preauthorization is not obtained before you receive Outpatient services, your claims may be denied as being not Medically Necessary. In such cases, you may be responsible for all charges. Therefore, you should make sure that you (or your provider) have obtained Preauthorization when required or predetermination of benefits when not required before you state Outpatient treatment.

Thus, the terms of Plaintiff's Plan require pre-approval for all psychiatric treatment. Prior to initiating TMS therapy, Plaintiff and Dr. Sutter sought pre-approval from the BCBS Plan's health insurance carrier, BCBSNM.

- 17. On or about June 27, 2013, BCBSNM (acting under the policies imposed on its divisions by HCSC) responded to the pre-authorization request by denying coverage for the proposed TMS therapy. According to the denial letter, BCBSNM's reason for denying coverage was "TMS NOT COVERED BY THIS GROUP -- VIEWED AS EXPERIMENTAL AND NOT CORPORATELY COVERED." The exclusion for "experimental" was the sole basis for the original denial.
- 18. Under Plaintiff's BCBS Plan, "Experimental or Investigational" services is a defined term. Under that definition, such services are those that are determined to be any of the following:

Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use;

Subject to review and approval by any institutional review board for the proposed use (Devices which are FDA approved under the Humanitarian Use Device exemption are not considered to be Experimental or Investigational); or the subject of an ongoing Clinical Trial that meets the definition of a Phase 1, 2 or 3 Clinical Trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight.

19. The TMS therapy proposed for Plaintiff did not meet this definition. In October 2008 the FDA provided market clearance for TMS therapy systems as a Class II Device for the treatment of Major Depressive Disorder, and such classification was codified at 21 C.F.R. \$882.5805. On April 30, 2013, the FDA confirmed that the NeuroStar TMS System was substantially equivalent to legally marketed predicate devices, and that the device's manufacturer, Neuronetics, Inc., was therefore permitted to market the device subject to the

general controls of the Federal Food, Drug and Cosmetics Act. The therapy is not subject to other institutional approval before it can be used. It is similarly not the subject of an ongoing Phase 1, 2 or 3 clinical trial.

- 19. Furthermore, TMS has been the subject of numerous studies, including recent large, multisite, randomized, sham-controlled clinical trials, supporting the clinical efficacy of TMS in the treatment of depression. TMS is in widespread use at major institutions like the Mayo Clinic–Rochester, the University of Michigan Depression Center, Walter Reed Army Medical Center, Brown University, UCLA, the Harvard medical system, Boston University Medical Center, Johns Hopkins University, Weill Cornell Medical School, Rush University and the University of South Florida. Various published, expert guidelines report on the evidence for TMS and recommend its use.
- 20. Following the original denial on grounds of TMS being "Experimental or Investigational," Plaintiff exhausted both of the two levels of appeal provided by the BCBS Plan. On each occasion, he provided detailed evidence through his treating psychiatrist, Dr. Sutter, of the need for TMS therapy for his particular case, of the approval of this therapy by the FDA, of the many distinguished institutions where the therapy is used, and of the extensive studies and literature showing its efficacy. On each occasion, Defendant ignored this evidence, and made no attempt to apply the facts of Plaintiff's case to the definition in the Plan of "experimental and investigational." Specifically:
- (a) On or about August 16, 2013, BCBSNM denied Plaintiff's initial appeal, based on the BCBS Plan's "Experimental and Investigational Services" exclusion. The purported basis for this determination was a clinical review performed by a "Dr. Parish," the available clinical documents, HCSC Medical Policy PSY301.015 (which states that TMS therapy is considered "experimental, investigational, and unproven"), and the BCBS Plan booklet. The letter made no

mention whatsoever of the FDA clearance, or the clinical studies and other evidence cited in Dr. Sutter's appeal letter. The letter quoted the definition of "Experimental or Investigational" contained in the BCBS Plan, but included no analysis of whether or how TMS therapy met the criteria set forth in this definition.

- (b) On or about October 15, 2013, BCBSNM rejected Plaintiff's second-level and final appeal, one day after holding a "DOL/ERISA Appeal Committee Review" meeting to consider that appeal. BCBSNM issued a letter reporting that the Appeal Committee decided, once more, to uphold the initial denial of coverage. The October 15, 2013 letter again cited, without analysis, HCSC Medical Policy PSY301.015 and the BCBS Plan's definition of "Experimental or Investigational." As with its initial denial, BCBSNM failed to address any of the evidence offered by Plaintiff and Dr. Sutter in the second-level appeal to demonstrate the proven effectiveness of TMS therapy in the treatment of clinical depression, and did not attempt to apply the facts of Plaintiff's case to the specific definition of "experimental or investigational" in the Plan. In the course of both these denials, the denial letters appear to try to defend the "Experimental and Investigational" denial not through this definition, but through asserting simply that therapy was not medically necessary in Plaintiff's case.
- 21. With the denial of his second-level appeal, Plaintiff exhausted his administrative remedies. BCBSNM's letter purported to complete its internal review process, and explicitly stated that "you also have the right to bring a civil action under 502(a) ERISA [sic] following the full internal review of your complaint."
- 22. Defendant failed to interpret and apply the terms of the BCBS Plan reasonably in denying coverage for the TMS therapy services requested by Plaintiff, in violation of its fiduciary obligations under ERISA, as follows:

- (a) The determination that TMS therapy is "experimental or investigational services" violated the terms of the Plan. Under no interpretation of the facts relating to TMS can that therapy be deemed "experimental or investigational" under the definition given in the Plan, or under any other reasonable interpretation of the words "experimental or investigational."
- (b) To the extent that Defendant, in the course of twice affirming the original "experimental and investigational" denial in the course of Plaintiff's two appeals, purported to rely on any other basis in the Plan for lack of coverage (such as the Plan's exclusion for services regarded as "not medically necessary"), that reliance was unreasonable, arbitrary and capricious, because it was expressly related by Defendant to its flat written policy of deeming TMS Therapy as "experimental and investigational." As these references show, any effort by Defendant to deny the medical necessity of TMS therapy in Plaintiff's or any other participant's case depends on its view that the therapy is "experimental and investigational." On information and belief, Defendant has never approved TMS therapy for any covered participant in an ERISA plan, regardless of how ineffective other forms of treatment for the participant's Major Depressive Disorder have been documented to have proved.
- 23. In addition to violating ERISA through its improper denial of coverage for TMS services, Defendant is also violating the Federal Parity Act by implementing a provision of the BCBS Plan covering Plaintiff which requires preauthorization on all mental health services, which thereby imposes an illegal restriction on such services. Despite the fact that the BCBS Plan imposes such preauthorization requirements on *all* behavioral health services, including inpatient and outpatient, the same requirements are not imposed on medical services in general. While preauthorization is required for all inpatient admissions for medical services, it is substantially limited to just a handful of limited outpatient medical services, as specified in the BCBS Plan:

Outpatient and Other Medical Services. Other nonemergency services (whether in-network...or out-of-network) that require BCBSNM Preauthorization are listed below...:

- Air ambulance services (except in an Emergency)
- Cardiac and pulmonary rehabilitation
- Cardiac CT scans
- Dental services stemming from Illness or Injury
- Durable Medical Equipment for items with a purchase or cumulative rental value of \$1,0000 or more
  - Insulin pumps and continuous glucose monitoring systems, regardless of costs
- Enteral nutrition/nutritional supplements
- Genetic testing (including breast cancer genetic testing (BRACA))
- Hearing aids/exams and/or cochlear implants
- Home dialysis
- Home health care
- Hospice care
- Infertility treatment
- Obesity surgery
- Positron emission tomography (PET) scans
- Reconstructive Procedures
- Short-term rehabilitation (includes inpatient rehabilitation facility, skilled nursing facility, Outpatient physical, occupational and speech therapy)
- Sleep disorder studies
- Transplant services, including pre-transplant evaluation....

Preauthorization requirements apply to both in-network...and out-of-network services, providers, and facilities. Preauthorization for the above-mentioned medical care services can be requested by calling BCBSNM....

- 24. As is evident from this list, the BCBS Plan only imposed preauthorization for medical outpatient services on a limited number of unique procedures, with the vast majority of medical outpatient services, including for chronic conditions like diabetes, heart disease or similar long term illnesses, not requiring the insured to obtain preauthorization prior to receiving services. In comparison, *all* outpatient mental health services must be preauthorized. Thus, by applying this BCBS Plan, Defendants are imposing substantially stricter requirements for mental health than for medical services in general.
- 25. Under the Federal Parity Act, and its accompanying regulations, mental health providers must be treated as comparable to primary care providers. Yet, under the BCBS Plan, Defendants do not require preauthorization and concurrent reviews for routine medical/surgical office visits, which medical/surgical providers are permitted to offer, subject (at most) only to retrospective review. This creates a disparity in coverage that is in violation of law.
- 26. Because Defendant makes all benefit determinations with regard to its BCBS Plans, it is a fiduciary under ERISA and must apply the Plans in a manner consistent with ERISA, including the Federal Parity Act, which has been incorporated into ERISA. In doing so, the ERISA provisions must be applied even if the explicit terms of the plan documents would otherwise require different conduct. Thus, even though the BCBS Plan applicable to Plaintiff includes a preauthorization requirement for all outpatient mental health services, Defendant has a fiduciary duty not to apply that provision because it discriminates against insureds seeking outpatient mental health services, in violation of the Federal Parity Act.

#### CLASS ACTION ALLEGATIONS

27. Plaintiff Sean Herring brings his claims on his own behalf and on behalf of a "TMS Class," defined as:

All participants or beneficiaries in ERISA Plans underwritten or administered by Defendant HCSC (or any of its operating divisions) who, during the relevant limitations period were denied health insurance coverage for TMS therapy services provided for treatment of clinical depression on grounds that included the assertion that it was "experimental or investigational."

- 28. The definition of "experimental or investigational services" in HCSC's health insurance policies at all relevant times has been either *verbatim* or substantially similar to the definition in the policy that provides coverage for Plaintiff's BCBS Plan.
  - 29. The TMS Class meets all requirements of F.R.Civ.P. 23(a) and 23(b). In particular:
- (a) The members of the TMS Class are so numerous that joinder of all members is impractical. While the precise number of members in this Class is known only to Defendant, Defendant is the fiduciary and has issued the policies providing coverage under tens of thousands of employer-sponsored ERISA plans, and TMS therapy has become so widespread that at a minimum, requests numbering in the thousands must have been submitted to and denied by Defendant for coverage of this therapy. The identities of the class members are readily identifiable. Defendant maintains claims databases that record each instance in which it denies coverage for TMS therapy for treatment of clinical depression. TMS therapy is described with a discrete set of procedure codes under the Current Procedural Terminology ("CPT") promulgated by the American Medical Association, and depression is likewise described with a discrete set of diagnostic codes under the Diagnostic and Statistical Manual of Mental Disorders ("DSM"). Accordingly, the members of the Class can be readily and objectively ascertained through use of records maintained by Defendant.

- (b) There exist issues of fact and law common to all members of this Class, the most obvious and important of which is whether TMS therapy is an "experimental or investigational service." The facts that determine the answer to this question do not vary among class members.
- (c) Plaintiff's claims are typical of the claims of the TMS class members because Defendant based its denial of coverage in Plaintiff's case on a medical policy that Defendant employs with respect to all requests for coverage for TMS therapy for treatment of clinical depression.
- (d) Plaintiff will fairly and adequately protect the interests of the members of the Class, is committed to the vigorous prosecution of this action, has retained counsel competent and experienced in class action litigation and the prosecution of ERISA claims, and has no interests antagonistic to or in conflict with those of the Class.
- (e) The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications which could establish incompatible standards of conduct for Defendant.
- (f) By applying a uniform medical policy treating TMS therapy services as "experimental, investigational or unproven," Defendant has acted and refused to act on grounds that apply generally to the Class.
- (g) A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all members of the Class is impracticable. Further, because the unpaid benefits denied class members may be small relative to the expense and burden of individual litigation, it would be impossible for the class members to redress individually the harm done to them.
- 30. In addition, Plaintiff brings his claims on his own behalf and on behalf of a "Preauthorization Class," defined as:

All participants or beneficiaries in ERISA Plans underwritten or administered by Defendant HCSC (or any of its operating divisions) who, during the relevant limitations period were subjected to preauthorization for outpatient mental health services.

- 31. This Class meets all relevant requirements of F.R.Civ.P. 23.
- (a) This Class is extremely large, making joinder impractical. Every year, Defendant processes tens if not hundreds of thousands of claims for mental health benefits from class members. Defendant maintains records of when it applies its preauthorization requirements to outpatient mental health services, which are also billed based on standing CPT codes.

  Accordingly, the members of the Class can be readily and objectively ascertained through use of records maintained by Defendant.
- (b) There are questions common to the Class, most obviously whether imposing preauthorization requirements on all outpatient mental health services, but not all outpatient medical services is a violation of the Federal Parity Act as incorporated into ERISA.
- (c) Plaintiff's claims are typical of the class of the Preauthorization class members because Defendant imposed the same preauthorization requirement on Plaintiff's outpatient mental health service, in violation of the Federal Parity Act as incorporated into ERISA.
- (d) Plaintiff will fairly and adequately protect the interests of the members of the Class, is committed to the vigorous prosecution of this action, has retained counsel competent and experienced in class action litigation and the prosecution of ERISA claims and has no interests antagonistic to or in conflict with those of the Class.
- (e) The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications which could establish incompatible standards of conduct for Defendant.

- (f) By applying a uniform policy requiring preapproval for all mental health services, Defendant has acted and refused to act on grounds that apply generally to the Class.
- (g) A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all members of the Class is impracticable. Further, because the unpaid benefits denied class members may small relative to the expense and burden of individual litigation, it would be impossible for the class members to redress individually the harm done to them.

## COUNT I CLAIM FOR BENEFITS DUE (on behalf of Plaintiff and the TMS Class)

- 32. The foregoing allegations are re-alleged and incorporated by reference as if fully set forth herein.
- 33. Count I is brought under 29 U.S.C. §1132(a)(1)(B), which authorizes a participant or beneficiary to bring a civil action to recover benefits due to him, to enforce his rights under the terms of a Plan, or to clarify his rights to future benefits under a Plan.
- 34. As an ERISA fiduciary, Defendant is obligated to administer benefits in accordance with the terms of the ERISA Plans.
- 35. Defendant violated the terms of the ERISA Plans by improperly applying the "experimental or investigational services" exclusion to TMS therapy services, thereby denying coverage and benefits otherwise owed to Plaintiff and the members of the TMS Class.
- 36. Plaintiff, on his own behalf and on behalf of the members of the TMS Class, seeks payment of the benefits owed by Defendant for coverage of TMS therapy services. Plaintiff further seeks an award of attorneys' fees, costs, prejudgment interest and other appropriate relief.

## COUNT II CLAIM FOR INJUNCTIVE RELIEF (on behalf of Plaintiff and the TMS Class)

- 37. The foregoing allegations are re-alleged and incorporated by reference as if fully set forth herein.
- 38. Count II is brought under 29 U.S.C. §1132(a)(3), which authorizes a participant or beneficiary to bring a civil action to enjoin or obtain other appropriate equitable relief to redress any act or practice which violates any provision of ERISA or the terms of an ERISA plan.
- 39. As alleged above, Defendant violated the terms of the ERISA Plans by improperly applying the "experimental or investigational services" exclusion to TMS therapy services based on internally developed guidelines, thereby denying coverage and benefits otherwise owed to Plaintiff and the members of the TMS Class.
- 40. Plaintiff, on his own behalf and on behalf of the members of the TMS Class, seeks a permanent injunction barring Defendant from treating TMS therapy services as "experimental or investigational" when provided to treat clinical depression. Plaintiff further seeks an award of attorneys' fees, costs, and other appropriate relief.

# COUNT III CLAIM FOR INJUNCTIVE RELIEF (on behalf of Plaintiff and the Preauthorization Class)

- 41. The foregoing allegations are re-alleged and incorporated by reference as if fully set forth herein.
- 42. Count III is brought under 29 U.S.C. §1132(a)(3), which authorizes a participant or beneficiary to bring a civil action to enjoin or obtain other appropriate equitable relief to redress any act or practice which violates any provision of ERISA or the terms of an ERISA plan.

- 43. As alleged above, Defendant violated ERISA by requiring Plaintiff and other members of the Preauthorization Class to receive preauthorization for all outpatient mental health services, contrary to the provisions of the Federal Parity Act.
- 44. Plaintiff, on his own behalf and on behalf of the members of the Preauthorization Class, seeks a permanent injunction imposing the preauthorization requirement on outpatient mental health services. Moreover, Plaintiff seeks an order requiring Defendant to permit all of the Preauthorization Class members of the right to submit claims relating to any outpatient mental health services received during the Preauthorization Class Period for reprocessing on a retrospective basis, without applying imposing time limitations on such claims that might otherwise apply. Plaintiff further seeks an award of attorneys' fees, costs, and other appropriate relief.

### PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in his favor against Defendant as follows:

- A. Certifying the Classes, as set forth in this Complaint, and appointing Plaintiff as Class Representative;
- B. Declaring that Defendant violated the ERISA Plans, and awarding appropriate benefits;
- C. Ordering Defendant to make payment, with interest, of unpaid benefits to Plaintiff and all TMS Class members;
- D. Permanently enjoining Defendant from treating TMS therapy services as "experimental or investigational" when provided to treat clinical depression;
- E. Declaring that Defendant violated the ERISA (and the Federal Parity Act), and awarding appropriate equitable relief;

- F. Permanently enjoining Defendant from requiring Plaintiff and members of the Preauthorization Class from obtaining preauthorization for outpatient mental health services;
- G. Awarding Plaintiff disbursements and expenses of this action, including reasonable attorneys' fees, in amounts to be determined by the Court; and
  - H. Granting such other and further relief as is just and proper.

/s/ George F. Galland, Jr.
George F. Galland, Jr.
One of the Attorneys for Plaintiff

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